Exhibit 11

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2	` IN THE UNITED STATES DISTRICT COURT
3	FOR THE NORTHERN DISTRICT OF OHIO
4	EASTERN DIVISION
5	X
	IN RE: NATIONAL PRESCRIPTION MDL No. 2804
6	OPIATE LITIGATION,
	Case No. 17-MD-2804
7	This document relates to:
8	All Cases Hon. Dan A. Polster
9	X
10	* HIGHLY CONFIDENTIAL *
11	* SUBJECT TO FURTHER CONFIDENTIALITY REVIEW *
12	VIDEOTAPED DEPOSITION
13	OF
14	LACEY R. KELLER
15	New York, New York
16	Thursday, June 13, 2019
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23	
	Reported by:
24	ANNETTE ARLEQUIN, CCR, RPR, CRR, RSA
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Page 14 Page 16 1 1 2 2 question I'm asking you, please absolutely If there are any exhibits that 3 3 feel free to tell me that, and I will do my folks would like me to put on the ELMO, 4 4 very best to rephrase it. I don't want the please just say so. 5 5 questions to be tricky. They're not BY MS. LEVY: 6 6 intended to confuse you. I would like to Q. Ms. Keller, have you seen this 7 make sure that you understand them before deposition notice before? 8 8 you answer them. A. No. 9 9 Can we agree that if you don't, Q. This is the first time you've 10 you'll ask me to rephrase? 10 taken a look at it? 11 A. Thanks. I will. 11 A. Yes. 12 12 Q. Okay. If you don't mind, please Q. Is there any reason that you 13 13 turn to the back page that says Exhibit A. can't give truthful, honest testimony 14 14 today? Exhibit A is a request for three 15 15 A. No. categories of documents. 16 16 Do you see that? Q. Okay. I'm going to ask you 17 17 questions. The attorneys that came with A. I do. 18 18 you today may object to questions that I Q. Okay. Let's start with No. 1, 19 19 ask. Unless they instruct you not to "All documents or other materials you 20 20 reviewed since the date of your report that answer, I would ask that you please answer 21 21 the questions. have not specifically been identified in 22 22 If they instruct you not to your report in preparation for your 23 23 answer, we'll probably quibble about that, expected testimony." 24 but you'll get to follow your counsel's 24 Do you see that? 25 25 advice on that; otherwise, we can take A. I do. Page 15 Page 17 1 1 2 2 Q. Have you prepared a list of breaks? 3 3 documents that would respond to No. 1? If you need a break at any time, 4 I would ask that you just answer any A. I believe I have. 5 pending question I have before we take a Q. Okay. I'm going to mark what 6 is -- I'm going to hand you what we're break. 7 7 going to mark as Exhibit 2. So if you need to use the 8 8 restroom or check your email or are hungry (Keller Exhibit 2, List of 9 9 or any of that, feel free to just tell me documents that respond to request 1 in 10 and we can take a break when we get to an 10 Exhibit A on Exhibit 1, marked for 11 11 identification, as of this date.) appropriate stopping point. 12 12 MS. LEVY: Okay. I would like to BY MS. LEVY: 13 13 mark as Exhibit 1, the deposition Q. Do you see Exhibit 2? 14 notice that was issued in this case. 14 A. I do. 15 15 (Keller Exhibit 1, Track 1 O. Take a look at that. Is 16 16 Exhibit 2 a list of documents that respond Defendants' Second Amended Notice of 17 17 Oral Videotaped Deposition of Lacey R. to request 1 in Exhibit A on Exhibit 1? 18 18 A. It's my intention that it does. Keller, marked for identification, as 19 19 of this date.) Q. Okay. That's what I figured. 20 20 MS. LEVY: Do you folks want How did -- who prepared 21 21 copies, physical copies of the Exhibit 2? 22 22 exhibits? If you do, just raise your A. Exhibit 2, I'm sorry, yes. I 23 23 hand. I'm going to pass them down did. 24 through Catie. And share them among 24 Q. And how did you prepare

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yourselves.

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Exhibit 2? What did you do to come up with

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2 2 So as I understand your opinions, 3 3 they are opinions from a data science point 4 4 of view that say if you ran these metrics, 5 5 here's what the results would look like. way. 6 6 Is that a fair assessment at a 7 7 very, very high level? MS. CONROY: Objection. 8 8 9 9 You can answer. Act, right? 10 10 A. I would say that's a fair 11 assessment. I was asked to apply the 11 12 12 compliance metrics to the labeler's data, 13 13 including chargebacks and IMS, IQ, yeah. 14 14 Q. And you don't intend to offer any 15 15 opinions about which one of those metrics that. 16 16 is the right one, do you? 17 17 A. That is correct. I don't endorse 18 18 any of the metrics or not endorse. 19 19 Agnostic would be the correct term, yeah. report? 20 20 Q. Okay. And you're not going to 21 21 offer any opinions that a particular 22 22 registrant should have or is required to 23 23 employ which ones of the metrics? That is 24 not what you were retained to do, correct? 24 25 25 A. That is correct. Page 51 1 1 2 Q. And that is beyond your expertise 3 3 to do. mean like... 4 4 Do you agree with that? 5 5 A. That is correct. 6 Q. And I think, if I'm reading your 6 7 7 report correctly, you don't take any 8 opinion as to what the DEA or the 8 9 9 Controlled Substances Act means when it 10 10 talks about suspicious orders. 11 11 You are not taking a position as A. Never. 12 12 to what specifically the DEA means, right? 13 13 A. Yes, I believe that's right. 14 Q. And I think it can make our day 14 15 15 easier if I understand the scope of this. 16 16 What you have done is you've used 17 17 a number of different metrics to show that 18 18 if a particular defendant had looked at the 19 19 data this way, this is what that defendant 20 20 would have seen. 21 21 Is that fair? 22 22 A. Yes. 23 23 Q. And when you use the term You can answer. "suspicious," which you do quite a number 24 24 25 25

that is the result of your own metrics,

A. Yes, you can characterize it that

Q. You don't mean to use "suspicious" as a technical term meaning suspicious under the Controlled Substances

MR. LEDLIE: Object to the form. You can answer.

- A. Yes, when I say "suspicious," I mean that they have either triggered one of the metrics, which are -- I'll leave it at
- Q. Okay. And you haven't, you haven't gone -- have you ever met with anyone from DEA about this case and your
- A. I have not met with anyone about this case or my report from the DEA.
 - Q. Okay. Why do you hesitate?
- A. I have spoken to DEA officials about the ARCOS data and how to process it, but clarifying questions of what does an S

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of times in your report, what you mean by

mean and what does this correction number

- Q. Okay. When you have spoken to the DEA, it has been entirely in the context of the data itself, correct?
 - A. Absolutely.
- Q. You've never asked anyone from DEA, "Do these various metrics make sense to you"? You've never asked that question?
- Q. And you've never asked anybody from DEA, "Are these metrics in line with what DEA expects or requires"? That's nothing you've ever asked the DEA, correct?
 - A. That is correct.
- Q. And that wasn't -- the point of your report is not to say what the DEA requires, but rather to say what the data had available for people to look at.

Is that a proper simplification? MS. CONROY: Objection.

A. I would say, yes, it was what data was available to apply the -- what

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data was available to apply the compliance metrics and what those metrics would have revealed.

Q. And, again, I think you've answered this, but I want to be sure.

You do not offer the opinion that any defendant had an obligation to apply any of the particular compliance metrics, right?

A. That is correct.

Q. And it is also beyond your expertise to opine on what would have happened in the real world if someone had applied the metrics? That is beyond what you are an expert in, correct?

MS. CONROY: Objection.

You can answer.

- A. Yes. There is a section in the report, the small labeler impact section, that, depending on how this question is worded, might come in conflict with that, but that's not the intention.
 - Q. We'll get to that. But just generally, in the small

DEA reporting requirements, do you?

- A. No.
- Q. And you don't know what triggers a reporting requirement for a manufacturer?

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- A. No.
- Q. You don't know what triggers a reporting requirement for a distributor, do you?
 - A. No.
- Q. And you don't know what triggers reporting requirements for pharmacies?
 - A. No.
- Q. It is beyond the scope of your expertise to opine on what triggers a reporting responsibility specifically? That's beyond what you have been asked to do here, correct?
 - A. Correct.
- Q. And also just to make sure we narrow in on what your opinions are, you are not an expert in what DEA does with suspicious reports? That is beyond your expertise as well, right?
 - A. That is correct.

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labeler impact, in your own words, you phrase it as a hypothetical, right?

- A. Correct.
- Q. You aren't suggesting -- the defendant that's subject to the small labeler impact is Janssen, correct?
 - A. Yes, I believe so.
- Q. And what you do in that section is you model, hypothetically, if Janssen had looked at the data this way, then hypothetically, orders could have been stopped, right?
 - A. That is correct.
- Q. But you do not go further in this report to opine that Janssen had an obligation to do that or should have done that or that the DEA expected Janssen to do that.

That's beyond your expertise, right?

- A. That is beyond, yes.
- Q. Okay. And, also, you don't know or you don't have the expertise to know -- you don't consider yourself an expert in

Q. And I think there are places in your report where you talk about orders that could have been stopped. And I just want to make sure that I understand the parameters of what you intend to say about that.

When you talk about orders that could have been stopped, you mean from a data perspective hypothetically, correct?

- A. Yes. I mean that the compliance metrics showed that order or that triggered that order and so, yes, it could have been stopped.
- Q. So someone, somewhere could have stopped those orders?
- A. Yes, they could have seen it or stopped it.
- Q. But beyond what the data shows, do you have any opinions whatsoever on how that would work in the real world?

MS. CONROY: Objection.

You can answer.

A. No, I have no opinions on the real world.

Page 86 Page 88 1 1 2 2 them separately, correct? didn't -- you were not asked to and you 3 3 A. That is correct. didn't look specifically at Allergan? 4 4 Q. And the reason you didn't is MS. CONROY: Objection. 5 5 because you were asked to assume these A. As far as we were presenting 6 6 groupings and to present the data this way; results, let's say, ala, table 1 and 2, 7 7 is that right? correct. 8 8 MS. CONROY: Objection. Q. Now beginning on page 16 in 9 9 A. Yes or from our own Section J, you describe your compliance 10 understanding. Yes. 10 metric application. 11 Q. Well, that's what I want to know. 11 Are you with me? 12 12 A. Yes. Which one was it? 13 13 With Allergan specifically, Q. And you state in paragraph 51, "I 14 because that's my client, were you asked to 14 was instructed by counsel to apply metrics 15 15 group it with Teva or did you independently derived and used by any manufacturer or 16 16 decide to do it that way? distributor and also to apply metrics 17 17 A. I would say it would be most applied in enforcement actions, McKesson 18 18 correct to say that we had grouped them and Masters, to all data sets to detect 19 19 from doing this for a long time and that it prescribing and purchasing patterns of 20 20 was agreed upon that that was okay. unusual size, frequency and pattern." 21 Q. Okay. 21 Do you see that? 22 22 A. So the data doesn't come that A. I do. 23 23 way. I have to process it and do the Q. When you say "I was instructed by 24 groupings. We presented the groupings. We counsel," who does that refer to? What 25 25 continued with those groupings as agreed counsel? Page 87 Page 89 1 1 2 2 A. That would refer to Linda Singer. upon. 3 3 Does that help? Q. And so when we talk about 4 Q. And so when you talk in table 7, 4 counsel, it's Linda Singer who asked you to 5 for example, about Allergan and you do 5 do these various metrics that we are going 6 break it out for table 7, what is the 6 to talk about in a minute? 7 7 difference there in Allergan and Teva? A. Linda Singer provided us with the 8 8 What Allergan products? assignment, yes. 9 9 A. I'm sorry, table 7? Q. In No. 1 -- well, this term that 10 Q. I'm sorry, my fault. Let me 10 is used in the end of paragraph 51, 11 11 "patterns of unusual size, frequency and reask the question. 12 12 Table 6. I keep saying 7, but pattern" and there is a cite there, what is 13 13 that cite? Do you know? it's table 6. 14 14 In table 6 on page 28, what I A. I understand that to be the Code 15 15 really would like to understand is what you of Federal Regulations when it comes to 16 16 diversion, but I'd have to have the actual understand the difference between Allergan 17 17 and Teva in that table? language in front of me to know. 18 18 A. So for that table, I think there Q. I don't mean to give you a memory 19 19 were -- the purpose of this table is to quiz on the cites. That is not the purpose 20 show compliance metrics over time, and so 20 of the question. 21 there were differences over time. 21 There are no specific 22 22 And so to the extent that we requirements for how a registrant is 23 23 could help show that granularity, that was supposed to calculate patterns of unusual

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the purpose of breaking them apart.

Q. But you didn't ask -- you

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size, frequency, and purchasing patterns of

a -- sorry, let me ask the question again.

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the purpose of breaking them apart.

Q. But you didn't ask -- you

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size, frequency, and purchasing patterns of

a -- sorry, let me ask the question again.

Page 90 Page 92 1 1 2 2 You are not aware of any specific Q. You do not know of any place in 3 3 rules or regulations for a registrant on the real world that applies that average, 4 how to calculate patterns of unusual size 4 correct? 5 5 or frequency, correct? MS. CONROY: Objection. 6 6 A. So I think, as I stated earlier, A. I wouldn't know. 7 that's not my area of expertise. Q. And it is not your opinion that 8 8 Q. And you're not aware of any? any registrant should have or had any 9 9 A. I wouldn't be able to say, but... requirement to employ that metric in the Q. Okay. The first metric that you 10 10 real world? That is not the opinion you're 11 11 employ is double the national average. And offering in this case, correct? 12 12 I'm looking now on page 17. A. Correct, that's not my area of 13 13 A. Correct. expertise. 14 14 Q. Are you with me? Q. Looking at No. 3, the McKesson 15 15 And that metric, again, was one 8,000 rule, again -- I apologize if this is 16 16 that Linda Singer asked you to do, correct? getting tedious. The McKesson 8,000 rule 17 17 A. Correct. is a metric that you are asked to apply by 18 18 Linda Singer, correct? Q. And you didn't find it in any DEA 19 19 regulations? A. Correct. 20 20 A. Correct. Q. And you were asked to look at 21 21 Q. You are not aware of any place in what would the data show if you used this 22 the real world where this metric is used, 22 set of assumptions, right? 23 23 MS. CONROY: Objection. correct? 24 MS. CONROY: Objection. 24 A. Yes. 25 25 A. I wouldn't know for sure. Q. Like No. 1 and 2, the McKesson Page 91 Page 93 1 1 2 2 Q. Do you have a guess? 8,000 rule is not a metric that you have 3 3 MS. CONROY: Objection. ever seen in any DEA guidance or 4 A. No. regulation, correct? 5 5 A. I think that's correct. Q. Okay. And you are -- I think you 6 already answered this earlier, but you are Q. Are you aware of any limitation 7 not offering any opinion that this metric anywhere in the DEA regulations or in the 8 Controlled Substances Act or any guidance is somehow a requirement on registrants, 9 9 right? That is not your opinion? interpreting them that puts a specific 10 A. Correct. That's not my area of 10 limitation on dosage units? 11 11 expertise. MS. CONROY: Objection. 12 12 Q. And you are not offering an A. I would say that's outside of my 13 opinion that failure to employ this metric 13 expertise. 14 is somehow unlawful or misconduct? 14 Q. And it is not your opinion in 15 15 this case that any particular defendant was That is beyond your expertise, 16 16 required or obligated to employ this metric correct? 17 17 in running its business, correct? A. Correct. 18 18 A. That's correct. That's outside Q. Going to the second metric that 19 19 you applied, triple national average, of my expertise. 20 again, that metric you were asked to run by 20 Q. Even with respect to McKesson, it 21 21 Linda Singer, correct? is outside your area of expertise to say 22 22 A. Correct. that anybody, McKesson or anybody else, had 23 23 Q. That did not come from any DEA a duty to run a metric in the way that you 24 guidance or any DEA regulations, correct? 24 have, right? A. Correct. 25 25 A. Yes, I believe that is correct.

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Q. Going down to No. 4, Maximum

Monthly Trailing Six-Month Threshold, which
in parentheses says, quote, "common sense."

I think you told me this before
the breek, common sense is not a term that

I think you told me this before the break, common sense is not a term that you came up with, right?

- A. Correct. I've heard this rule referred to colloquially as the common sense rule.
- Q. Who have you heard that colloquially? Who has referred to this rule as the common sense rule?
- A. I honestly couldn't remember. It's been -- I've heard it so many times that I --
- Q. Had you heard it from lawyers in the case?
 - A. Sure.

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- Q. Have you ever heard it from DEA?
- A. No. Like I said, I only spoke to the DEA about the ARCOS data.
- Q. Okay. And it is not your opinion in this case that this metric is the most sensible metric? Even though the term

I have there, that's where it would have been derived from.

Q. And beyond that, you don't know anything other than you were asked to run it, correct?

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- A. Yeah, I was asked to review the metric and implement it on the data.
- Q. With respect to the Qualitest Endo 25/50 percent national average, that metric also came -- that metric was presented to you by the attorneys as something that you should run based on documents that you were provided, correct?
- A. It was either a metric that we found or the attorneys provided. I honestly can't remember.
- Q. And for this metric, which was it? Did you stumble across a document and say, hey, we should run this? Or did the attorneys provide you documents and say based on these documents, we'd like for you to run it as if this were the law of the land?

MS. CONROY: Objection.

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might suggest that, that's actually not your opinion in this case. Am I right about that?

- A. That's correct.
- Q. Okay. Have you read the Masters Pharmaceutical opinion from the D.C. circuit in 2017?
 - A. I think I skimmed it a while ago.
- Q. You don't intend to offer any opinions about what the law is as a result of that opinion, correct?
 - A. That's correct.
- Q. And you don't intend to offer any opinions as to what the law might require as a result of that opinion, do you?
 - A. That's correct.
- Q. Okay. Sorry, back to the common sense threshold. That is not a threshold that came from -- where did that threshold come from?
- A. Do you mean where was the metric derived or?
 - Q. Yes. Where was metric derived?
 - A. So I have it -- whatever citation

A. I'd really have to review my notes to know for sure. I don't remember.

Q. Okay. And you don't recall seeing this metric in any directive from DEA or any guidance from DEA? That's not your opinion in this case?

A. That's correct. I don't recall seeing it in any guidance, nor is it my opinion to offer.

- Q. And I think, to short-circuit this, if we look at page 19, 20, 21, and 22 of your report, those list other metrics that you were asked to run, correct?
- A. Yes. I would say I was asked to review the documents, interpret the metrics and run them on the data.
- Q. You will not offer any opinion in this case as to whether these metrics are appropriate for a registrant to do in real life, whether a registrant should have done them or had any requirement to do them in real life? That is outside of the scope of the opinions you intend to offer in this case, correct?